Department of Veterans Affairs **VHA DIRECTIVE 2005-047**
Veterans Health Administration
Washington, DC 20420 **October 21, 2005**

INFLUENZA VACCINE RECOMMENDATIONS FOR 2005-2006

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy and implementation guidance on the use of influenza vaccine for 2005-2006.

2. BACKGROUND

a. The influenza vaccination program is an essential component of VHA's health promotion and disease prevention programs. Influenza is a cause of substantial morbidity and mortality in the United States. The influenza vaccine is the most effective way to protect against influenza disease and resultant potentially severe complications. VHA has made influenza vaccination a priority. Vaccination of veteran patients reduces the risk of influenza for them, helps protect their families, and can keep them from transmitting influenza to other patients and staff in health care facilities. Vaccination of health care facility staff in close contact with patients can also reduce transmission of influenza and subsequent influenza-related complications to patients, co-workers, and family members. Influenza vaccination is a safe and cost-effective means for preventing and controlling influenza. ***NOTE:*** *Influenza vaccination rates of veteran patients are monitored in the VHA performance measurement system.*

b. The 2005-2006 trivalent vaccine virus strains are A/California/7/2004 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/Shanghai/361/2002-like antigens. There are antigenically equivalent viruses that may be used by manufacturers in preparation of influenza vaccine.

c. Effective July 1, 2005, trivalent influenza vaccines became covered vaccines under the National Vaccine Injury Compensation Program (VICP) and have been added to the Vaccine Injury Table that lists the vaccines covered under VICP. As required by Federal law under the National Childhood Vaccine Injury Act, all health care providers who administer any vaccine covered by the VICP must provide a copy of the relevant current edition of vaccine information materials (specifically Vaccine Information Statements (VIS)) prior to administration of each dose of the vaccine. VIS are developed by the Centers for Disease Control and Prevention (CDC) and are available from the CDC websites at:
http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf , and
http://www.cdc.gov/nip/publications/VIS/vis-flulive.pdf. A copy must be provided to the parent or legal representative of any child to whom the provider intends to administer such vaccine, and to any adult to whom the provider intends to administer such vaccine. The materials must be supplemented with visual presentations or oral explanations, as appropriate. ***NOTE:*** *When the final VIS is issued by CDC, VHA will provide copies that can be ordered from the Service and Distribution Center. Facility Publication Control Officers will be provided ordering information when these are available.*

THIS VHA DIRECTIVE EXPIRES ON DECEMBER 31, 2006

3. POLICY: It is VHA policy to base the influenza vaccination program on recommendations of the CDC Advisory Committee on Immunization Practices (ACIP) as published in Morbidity and Mortality Weekly Report (MMWR), while focusing on VHA specific issues in accordance with statues or other regulations, and policies governing vaccine administration to patients and employees.

4. ACTION: VHA facility Directors are responsible for implementing an influenza vaccination program in accordance with this Directive, updates from CDC, and any Department of Veterans Affairs (VA) Influenza Vaccine Advisories from VA's Under Secretary for Health to ensure alignment with the following:

a. **Target Groups for Vaccination**

(1) Persons at increased risk for complications from influenza are:

(a) Adults aged 65 years and older;

(b) Residents of nursing homes and other chronic-care facilities;

(c) Persons who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;

(d) Persons who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus (HIV));

(e) Persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of their respiratory secretions or that can increase the risk for aspiration;

(f) Children aged 6 months to 18 years who are on long-term aspirin therapy;

` (g) Children aged 6 to 23 months; and

(h) Women who will be pregnant during the influenza season.

(2) Persons in an age group that has an increased prevalence of persons with high-risk conditions, to include persons aged 50 to 64 years,

(3) Persons who can transmit influenza to those at high risk,

(a) Health-care workers,

(b) Employees of assisted living and other residences for persons in groups at high risk,

(c) Persons who provide home care to persons in groups at high risk, and

(d) Household contacts of persons in groups at high risk.

(4) Travelers to the tropics, with organized tourist groups at any time of year, or to the Southern Hemisphere during April through September.

(5) General population, including any person who wishes to reduce the likelihood of becoming ill with influenza or transmitting influenza to others (depending on vaccine availability)

NOTE: *Depending upon vaccine availability, it may be necessary for tiered timing of vaccination of different groups as announced by CDC and VA's Under Secretary for Health through Influenza Vaccine Advisories.*

b. **Those Who Should Not be Vaccinated.** There are some people who should not be vaccinated. These include:

(1) People who have a severe allergy to chicken eggs,

(2) People who have had a severe reaction to an influenza vaccination in the past,

(3) People who developed Guillain-Barre′ syndrome (GBS) within 6 weeks of getting an influenza vaccine previously,

(4) Children less than 6 months of age, and

(5) People who are sick with a fever (these people can get vaccinated once their symptoms lessen).

c. **Influenza Vaccines.** There are two trivalent influenza vaccines available for use in the United States, inactivated vaccine (given as an intramuscular injection) and live, attenuated influenza vaccine (LAIV) (which is administered intranasally). Both vaccines are to be given in alignment with the package inserts provided by the manufacturers, CDC recommendations, and VHA Influenza Vaccine Advisories. ***NOTE:*** *Information pertinent to influenza vaccines can be found in the VA Influenza Toolkit Manual 2005-2006 at:* http://www.publichealth.va.gov/flu . Health care providers must give the most current and appropriate Vaccine Information Statement developed by CDC to patients, parents, legal representatives, and/or employees prior to administration of either inactivated influenza vaccine or live, attenuated influenza vaccine.

(1) Inactivated influenza vaccine is recommended for persons at increased risk for complications from influenza (see subpar. 4a(1), and subpar. 4a(2)(a) for persons aged 50 to 64 years).

(2) Live, attenuated influenza vaccine can be administered to healthy persons aged 5 to 49 years who are not contacts of severely-immunosuppressed persons.

d. **Patient Consent and Documentation.** All persons receiving trivalent influenza vaccines must receive information about the vaccine and be given a copy of the most current and appropriate VIS (VIS for inactivated influenza vaccine or VIS for live, attenuated influenza vaccine) prior to administration of the vaccine. The practitioner who has primary responsibility for the patient, or who will perform the procedure, must explain in language understandable to the patient or surrogate the nature of the procedure, expected benefits, reasonably foreseeable associated risks, complications or side effects, anticipated results if influenza vaccine is not given, and must document the non-signature informed consent process in the medical record.

(1) Documentation must include the:

(a) Date of administration of the vaccine,

(b) Lot number,

(c) Manufacturer,

(d) Route and site of vaccine administration,

(e) Name and title of the individual administering the vaccine, and

(f) Specific CDC VIS provided indicating the edition date of the materials and the date the VIS was provided.

(2) Administration of influenza vaccine to veteran patients must be documented in the computerized patient records system (CPRS) in the immunization section.

e. **Employee Consent and Documentation.** Any employee who receives a trivalent influenza vaccine from VA must receive information about the vaccine (CDC's VIS). The information is to include the nature of the procedure; expected benefits; reasonably foreseeable associated risks, complications, or side effects; and anticipated results if influenza vaccine is not given. Documentation is to include employee receipt of the specific VIS provided indicating the edition date of the material and the date it was given to the employee, lot number, manufacturer, route and site of vaccine administration, and name and title of the individual administering the vaccine. Documentation and maintenance of employee health records concerning influenza vaccine must be in accordance with VA Handbook 5019, Part V. Provision of influenza vaccine to employees, as appropriate, will be at no expense to the employee. An adverse event related to voluntary participation in an employee influenza vaccination program is not a work-related Occupational Safety and Health Administration (OSHA) recordable event. This exclusion does not affect eligibility for Office of Workers' Compensation Programs (OWCP) claims. ***NOTE:*** *The facility is expected to provide data to VA Central Office on the percent of employees who have received influenza vaccine.*

f. **Adverse Events Related to Vaccine Use are Reported.** All serious adverse drug events relating to biologicals at the facility, must be reported to the Food and Drug Administration (FDA) on a completed FDA Form 3500, Med Watch. Reports of adverse events related to vaccine use need to be reported to FDA on form VAERS – 1, Vaccine Adverse Event Form.

g. **Vaccine Shortage.** Influenza vaccine distribution delays or vaccine supply shortages have occurred in the United States in three of the last five influenza seasons. Due to several uncertainties regarding the upcoming influenza season (influenza vaccine supply, demand for vaccine, severity of the influenza season, etc.), there is a need to follow guidelines as communicated by CDC and through VA Influenza Vaccine Advisories. If an influenza vaccine delay and/or shortage occurs, VHA facilities at the local level need to develop a prioritization plan in accordance with the aforementioned guidelines.

h. **Strategies for Implementing Vaccination Recommendations in Health Care Settings.** Program planning must be undertaken for a successful vaccination program. To assist with program planning, VA has published a VA Influenza Toolkit Manual for 2005-2006 influenza season that has been distributed to each VA medical center and is available on-line at: http://www.publichealth.va.gov/InfectionDontPassItOn/. Vaccination program strategies can also be found in "Recommendations of the Advisory Committee on Immunization Practices (ACIP)," MMWR. July 29, 2005:Vol. 54 RR8; 1-44, which may be found at: http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf.

i. **Antiviral Agents for Influenza.** Antiviral drugs for influenza are an adjunct to influenza vaccine for controlling and preventing influenza. However, these agents are not a substitute for vaccination. Four licensed influenza antiviral agents are available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir. Since the four drugs differ in pharmacokinetics, side effects, routes of administration, approved age groups, dosages, and costs, administration of the drugs needs to be in alignment with the package inserts provided by the manufacturers and the most recent CDC guidelines for usage.

5. REFERENCES

a. CDC. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," MMWR. July 29, 2005:Vol. 54 RR8; 1-44, at: http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf

b. CDC. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," MMWR. July 29, 2005:Vol. 54, No. RR-8, MMWR. August 5, 2005:Vol. 54(30); 750, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a6.htm.

c. CDC. "Tiered Use of Inactivated Influenza Vaccine in the Event of a Vaccine Shortage," MMWR. August 5, 2005:Vol. 54(30; 749-750, at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a4.htm.

d. CDC. Inactivated Influenza Vaccine, Vaccine Information Statement at: http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf.

e. Live Intranasal Influenza Vaccine, Vaccine Information Statement at: http://www.cdc.gov/nip/publications/VIS/vis-flulive.pdf.

f. Influenza (Flu) at: http://www.cdc.gov/flu/.

g. Public Health Information from VA. Influenza (Flu). http://www.publichealth.va.gov/flu/.

h. VA Influenza Vaccine Advisories at: http://www.publichealth.va.gov/flu/ .

i. VA Influenza Toolkit Manual 2005-2006 at: http://www.publichealth.va.gov/flu .

j. U.S. Department of Labor, Occupational Health and Safety Administration (OSHA). Regulations (Title 29Code of Federal Regulations - Standards) Determination of Work-relatedness, Standard 1904.5, at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9636.

k. Title 42 United States Code. Chapter 6A, Subchapter XlX, Vaccines, at: http://www4.law.cornell.edu/uscode/42/ch6AschXIX.html.

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11), is responsible for the contents of this Directive. Questions relating to influenza and/or influenza vaccine may be referred to the Infectious Diseases Program Office at (513) 475-6398.

7. RECISION: VHA Directive 2004-052 is rescinded. This VHA Directive expires on December 31, 2006.

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